

Package leaflet: Information for the user
Morphine Sulfate 20mg/ml Oral Solution

Morphine Sulfate

(Referred to as Morphine Sulfate Oral Solution in the remainder of the leaflet)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Morphine Sulfate Oral Solution is and what it is used for
2. What you need to know before Morphine Sulfate Oral Solution is given
3. How Morphine Sulfate Oral Solution is given
4. Possible side effects
5. How to store Morphine Sulfate Oral Solution
6. Contents of the pack and other information

1. What Morphine Sulfate Oral Solution is and what it is used for

The name of your medicine is Morphine Sulfate 20mg/ml Oral Solution (called Morphine Sulfate Oral Solution in this leaflet).

- It contains a medicine called morphine sulfate. This belongs to a group of medicines called ‘opioid analgesics’
- It is used to relieve severe pain

2. What you need to know before Morphine Sulfate Oral Solution is given

Do not take Morphine Sulfate Oral Solution if:

- you are allergic to morphine sulfate or any of the other ingredients of this medicine (listed in Section 6)
- you have problems with your lungs or breathing such as ‘hypoventilation’ or ‘Chronic Obstructive Pulmonary Disorder’ (COPD)
- you are having an asthma attack
- you have sudden or recent liver problems
- you have recently had a head injury
- you have something called ‘phaeochromocytoma’. This is a rare tumour which is not malignant
- you have fits (convulsions) or raised pressure inside your skull
- the person taking the medicine is in a deep and prolonged unconscious state (coma)
- you are addicted to alcohol or have recently consumed large amounts of alcohol
- you are taking or have in the last two weeks taken medication to treat depression such as monoamine-oxidase inhibitors (MAOI)
- you have paralytic ileus (loss of intestinal movement)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Take special care with Morphine Sulfate Oral Solution

Talk to your doctor or pharmacist before taking **Morphine Sulfate Oral Solution** if:

- You are pregnant, trying to become pregnant or if you are breast-feeding
- You have had an operation within the last 24 hours
- You have a particular lung problem that causes shortness of breath called emphysema
- You have shock (circulatory failure)
- You have asthma
- You have gall bladder problems
- You have long term (chronic) liver or kidney problems
- You are a man who has prostate problems
- You have an under-active thyroid gland or swelling of your skin (myxoedema)
- Your spine is unusually curved (kyphoscoliosis)
- You have bowel problems
- You have an under-active adrenal gland (adrenocortical insufficiency)
- You are very overweight

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Morphine Sulfate Oral Solution.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Morphine sulfate Oral Solution:

- Increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or a change in strong analgesic (“painkiller”), (see section 2).
- Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take hormone supplement.
- Loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production.
- If you have once been dependent on drugs or alcohol. Also tell if you feel that you are becoming dependent on Morphine sulfate Oral Solution while you are using it. You may have started to think a lot about when you can take the next dose, even if you do not need it for the pain.
- Abstinence symptoms or dependence. The most common abstinence symptoms are mentioned in section 3. If this occurs, your doctor may change the type of medicine or the times between doses.

Other medicines and Morphine Sulfate Oral solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Morphine Sulfate Oral Solution can affect the way some other medicines work. Also some other medicines can affect the way Morphine Sulfate Oral Solution works. In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to help you sleep, make you feel less anxious or calm you down such as tranquilisers, hypnotics, sedatives, antipsychotics or tricyclic antidepressants

- Anaesthetics - used during operations
 - Domperidone and metoclopramide - for feeling sick (nausea) and being sick (vomiting)
 - Mexiletine and esmolol - for controlling heart rhythm
 - Ritonavir - for HIV infections
 - Cimetidine - for stomach ulcers, indigestion or heartburn
 - Monoamine oxidase inhibitors (MAOIs) - for depression
 - Voriconazole - for some fungal infections
 - Gabapentin - for epilepsy and long lasting pain caused by damage to the nerves
 - Rifampicin to treat e.g. tuberculosis
- Concomitant use of Morphine sulfate Oral Solution and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Morphine sulfate Oral Solution together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Morphine Sulfate Oral Solution with food and drink

You should avoid alcohol whilst taking this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant or trying for a baby you should not be given this medicine unless your doctor believes the benefits outweigh the potential risks. If you take this medicine during pregnancy or while breast-feeding, it may slow down the baby's breathing.

If Morphine sulfate Oral Solution is used for a long time during pregnancy, there is a risk of the new-born child having drug withdrawal (abstinence) symptoms which should be treated by a doctor.

Men, and women who could become pregnant, must use reliable contraception while using Morphine Sulfate Oral Solution.

You should not breast-feed during your treatment with this medicine as morphine is known to pass into breast milk.

Operations and anaesthetics

Tell your doctor or pharmacist if you are due to have an operation or anaesthetic or if you have had an operation or an anaesthetic within the last 24 hours.

Driving and using machines

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected.

There is further information for patients who are intending to drive in Great Britain – go to <https://www.gov.uk/drug-driving-law>

Morphine Sulfate Oral Solution contains Amaranth(E123), Sodium and Sodium Benzoate

Amaranth(E123):

This medicine may cause allergic reactions.

Sodium and Sodium Benzoate:

This medicine contains less than 1mmol sodium (23mg) per ml, that is to say essentially 'sodium-free'.

This medicine contains 1mg Sodium Benzoate in each ml.

3. How Morphine Sulfate Oral Solution is given

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Use the oral syringe provided to measure your dose
- Place the bottle adaptor into the bottle neck then place the syringe in the solution and pull the white plunger up so that liquid is drawn up into the syringe
- Draw the liquid into the syringe until it is level with the mark which shows your required dose. The marks are in mls of liquid
- You may prefer to add your dose to a soft drink. If you do this, it should be swallowed immediately after mixing.

How much to take

Your doctor will decide the amount of medicine to give you.

Adults

- The usual dose is 0.5 to 1 ml (10-20 mg) every four hours

Paediatric population

Children 13 to 18 years

- The most that should be taken is 0.25 to 1 ml (5-20 mg) every four hours

Children 6 to 12 years

- The most that should be taken is 0.25 to 0.5 ml (5-10 mg) every four hours

Children 1 to 5 years

- The most that should be taken is 0.25 ml (5 mg) every four hours

Children under 1 year

- Do not give this medicine to children under 1 year

Being given more or less of this medicine

- For some people, it may be necessary for the doctor to give a higher dose
- For other people (for example the elderly, people with kidney or liver problems and people that should not be sedated) the doctor may decide to use a lower dose

Your body may get used to the medicine (tolerance)

- Do not take more than your doctor has prescribed
- If you have been taking your medicine for some time you may find that it does not seem to be working as well as it did. If this happens, talk to your doctor

If you take more Morphine Sulfate Oral Solution than you should

If you take more of this medicine than you should, talk immediately to a doctor or go to a hospital straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you take more than you should, the following effects may happen:

- The black circle in the centre of your eyes (pupil) gets smaller
- You breathe more slowly or have breathing difficulties
- You get tired or sleepy

In more severe cases, your blood circulation may slow down and shock, coma or even death may occur.

In children a high dose may cause fits (convulsions).

A pneumonia from inhaling vomit may occur subsequently after overdose.

If you forget to take Morphine Sulfate Oral Solution

- If you forget a dose, take it as soon as you remember it and take your next dose at the usual time
- If it is nearly time for the next dose, skip the missed dose. This is because the time between doses should be at least 4 hours
- Do not take a double dose to make up for a forgotten dose

If you stop taking Morphine Sulfate Oral Solution

It is important to talk to your doctor if you want to stop taking your medicine. Do not stop taking your medicine suddenly. This is because your body may have got used to it. Also, you may need to have your dose lowered slowly. If you want to stop the treatment with Morphine sulfate Oral solution, ask your doctor how to slowly decrease the doses so you avoid abstinence symptoms. Abstinence symptoms may include body aches, tremors, diarrhoea, stomach pain, nausea, flu-like symptoms, fast heartbeat and large pupils. Psychological symptoms include an intense feeling of unsatisfaction, anxiety and irritability.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, Morphine Sulfate Oral Solution can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions

If you have a severe allergic reaction, stop taking this medicine and see a doctor straight away. Signs may include swelling of the mouth and face, difficulty breathing, dizziness and skin reactions such as rash and itching.

Tell your doctor straight away if you notice the following side effects.

You may need urgent medical treatment:

- Having a headache. This could be a sign of raised pressure inside your skull
- Feeling dizzy or unsteady when you stand up. This could be a sign of a temporary fall in blood pressure (orthostatic hypotension)
- Shallow breathing, with a slow heartbeat (bradycardia) and cold clammy skin
- Feeling restless, irritable or having changes in your mood
- Stomach pain caused by spasm (cramps) of the tubes that carry urine to the bladder or bile to the intestines

Other side effects

- Feeling sick (nausea) or being sick (vomiting)
- Constipation, which can be treated with appropriate laxatives
- Difficulty in passing water (urine)
- Feeling drowsy
- Dry mouth, sweating and flushing of your face
- Your heart rate getting faster (tachycardia) or slower (bradycardia) or fast and uneven (palpitations)
- Lower body temperature (hypothermia)
- Lowered sex drive
- Seeing or hearing things that are not there (hallucinations) or feeling confused
- Muscles feeling tense
- The black circle in the centre of your eyes (pupil) getting smaller (miosis)
- Abstinence of symptoms or dependence on Morphine Sulfate Oral Solution (for symptoms see section 3: If you stop taking Morphine Sulphate Oral Solution). This can happen with any morphine product

Not Known: frequency cannot be estimated from the available data

- An increased sensitivity to pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517;

Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Morphine Sulfate Oral Solution

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original container in order to protect from light.

Do not use this medicine after the expiry date which is stated on the bottle label and the outer carton. The expiry date refers to the last day of the month.

Once opened the product should be used within four months. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Morphine Sulfate Oral Solution contains

- Each ml contains 20 mg of morphine sulfate as the active ingredient
- The other ingredients are disodium edetate, sodium benzoate (E211), citric acid anhydrous, amaranth (E123) and purified water.

What Morphine Sulfate Oral Solution looks like and content of the pack

Morphine Sulfate Oral Solution is a clear pink solution. The finished product is packed in 120ml, 50ml and 30ml amber soda glass bottles fitted with a white polypropylene push and turn, tamper evident cap.

In addition the product is supplied with a 1ml dispensing oral syringe and bottle adaptor.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This Medicinal Product is authorised in the Member States under the following names:

UK & Ireland: Morphine Sulfate 20mg/ml Oral Solution

Germany: Morphin Aristo Lösung 20mg/ml

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Morphine Sulfate 20mg/ml Oral Solution	29831/0524

This is a service provided by the Royal National Institute of Blind People.

For the Republic of Ireland please call + 44 1978 661261

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